

# FDA COMMUNICATIONS PLAN

## 1. Immediate communication to CFSAN within FDA

- Office of Premarket Approval, Division of Petition Control
- \* Phone call to alert them to issue and explain TSCA 8(e) submission
- \* Possible follow-up letters, if requested
- \* Schedule meeting for full disclosure ASAP
- \* Multiple meetings likely

## 2. Plan to Address Issue

- migrate to product with no migration*
- Start here*
- ~~X~~ Intent to have orderly exit from the market
  - Define size and extent of business
  - Disclose metabolism study and general finding of PFOS in sera
  - Provide summary of existing tox testing and planned tox testing
  - Provide summary of 3M plant worker studies
  - Provide plan to **immediately** reduce levels of "contaminants" in product X% and set absolute release specifications
  - Address pending microwave popcorn petition
  - Shift product mix to minimize exposure
  - No new business (product or regions)
  - *Timing - give definition*
- eliminate*

Exhibit  
1488

State of Minnesota v. 3M Co.,  
Court File No. 27-CV-10-28862

# EPA COMMUNICATION PLAN

1. Corporate TSCA 8(e) committee met 2/13/98

- Consensus to file 8(e) to EPA
- Based on:
  - (1) metabolism study identifying additional routes of exposure through metabolism of other chemistries
  - (2) finding PFOS in sera from the general population not exposed occupationally

only facts

2. TSCA 8(e) submission completed

- Describes only metabolism study and finding of FC in sera
- References communication to FDA

3. Plan

- File 8(e) on or before 3/6/98
- Call EPA in advance of submission
- Arrange meeting for full disclosure ~ late March, early April
- Maintain consistent communication with EPA as additional information is developed

4. Issues associated with 8(e) filing

- **Public disclosure** (environmental activist, regulatory newsletters)
- **Must** coordinate with FDA communications

5. 8(e) submissions also include environmental hazards

- We are making analytical measurements at Decatur facility and mass balance evaluations to assess environmental aspects of this issue. Could trigger